Shorter treatment for Chagas disease could be just as effective, and significantly safer

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Patients wait to be attended at the Bolivian Platform for Chagas Disease in Cochabamba. Credit: Ana Ferreira

A two-week treatment course for adult patients with chronic Chagas disease showed similar efficacy and significantly fewer side effects than

the standard treatment duration of eight weeks when compared to placebo, according to the results of a clinical trial in Bolivia led by the Drugs for Neglected Diseases initiative (DNDi).

Chagas disease affects an estimated 6 million people globally and can lead to irreversible damage to vital organs, and death. Benznidazole, one of the two drugs used to treat Chagas, is traditionally administered twice a day over a course of eight weeks, in line with PAHO and WHO recommendations and national guidelines.

The Phase II clinical trial, carried out in three centres in Bolivia, sought to improve safety, tolerability and efficacy of treatment with this drug, which was discovered a half-century ago. Initiated in 2016, it was the first-ever placebo-controlled study to test various lengths and dosages of treatment with benznidazole, both on its own as a monotherapy, and in combination with fosravuconazole.

The results were presented for the first time today at the XV Workshop on Chagas Disease, organised by the Barcelona Institute for Global Health. "We believe treatment can spare people with Chagas the risk of a lifetime of debilitating complications associated with the disease. However, the current treatment can cause severe side effects, which has often discouraged some people from seeking treatment and healthcare workers from recommending it," said Joaquim Gascon, a principal investigator in the trial and the director of the Chagas Initiative at ISGlobal.

"We've shown that shorter treatment could be just as effective, and much safer. This could change the paradigm for Chagas treatment, by improving adherence and encouraging wider adoption by the medical community," said Dr. Faustino Torrico, President of CEADES Foundation, Bolivia, and a principal investigator in the trial.

All arms of the study, both monotherapy and combination, were shown to be efficacious. Eighty percent of the patients assigned to the group that took the standard dose of 300mg/day of benznidazole for two weeks instead of the standard eight weeks showed no sign of the parasite in their blood six and 12 months after finishing the treatment. A similar result was observed in the group that took the standard eight-week treatment.

Significantly, none of those in the two-week reduced duration group interrupted treatment On average, 2 in 10 patients who followed the standard course of treatment with benznidazole abandoned the treatment due to side effects.

"These results bring new hope for people living with this silent disease and could change the reality of access to treatment in endemic countries. With a much simpler treatment regimen, there is no excuse for not treating people with Chagas disease," said Dr. Sergio Sosa Estani, Head of Chagas Clinical Programme at DNDi. "DNDi will now continue to work with national programmes, partners and ministries of health of endemic countries to confirm these results and encourage necessary steps to register the new regimen and turn this breakthrough discovery into a reality for people affected by the disease."

DNDi continues to work on pre-clinical and clinical research to discover, develop, and test new drugs and drug combinations to treat Chagas.

About the study

The Benznidazole New Doses Improved Treatment & Associations (Bendita) study was carried out in sites in Cochabamba, Tarija and Sucre, Bolivia. It tested six treatment arms with a variety of lengths and dosages of benznidazole against a placebo, both as a monotherapy and in combination with fosravuconazole:

- The standard 8-week treatment, with a standard daily dose of 300mg/day of benznidazole in monotherapy
- A 4-week treatment with a daily dose of 300mg/day of benznidazole in monotherapy
- A 2-week treatment with a daily dose of 300mg/day of benznidazole in monotherapy
- A 4-week treatment with a lower daily dose of 150mg/day of benznidazole in monotherapy
- A 4-week treatment with a lower daily dose of 150mg/day of benznidazole, in combination with fosravuconazole
- An 8-week treatment, with a lower weekly dose of 300mg of benznidazole, in combination with fosravuconazole.

Efficacy was measured through sustained parasitological response at six months, with a final assessment at 12 months after the end of the treatment.

Provided by Barcelona Institute for Global Health

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